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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS-2017-0008]

Public Health Information System (PHIS) Export Component Country Implementation

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing and requesting comment on its plan to implement the Public Health Information System (PHIS) Export Component. In response to stakeholder feedback and to ensure sufficient testing and outreach, FSIS is extending the implementation date of the PHIS Export Component to June 29, 2018. FSIS will first implement the PHIS Export Component with a limited number of foreign countries and will expand implementation to add countries incrementally.

DATES: Submit comments on or before October 6, 2017.

ADDRESSES: FSIS invites interested persons to submit comments on issues discussed and outlined in this notice. Comments may be submitted by one of the following methods:

Federal eRulemaking Portal: This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to <http://www.regulations.gov/>. Follow the on-line instructions at that site for submitting comments.

Mail, CD-ROMs: Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, Patriots Plaza 3, 1400 Independence Avenue SW., Mailstop 3782, Room 8-163B, Washington, DC 20250-3700.

Hand- or courier-delivered submittals: Deliver to Patriots Plaza 3, 355 E Street SW., Room 8-163A, Washington, DC 20250-3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2017-0008. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to <http://www.regulations.gov>.

Docket: For access to background documents or to comments received, go to the FSIS Docket Room at Patriots Plaza 3, 355 E Street SW., Room 164-A, Washington, DC 20250-3700 between 8:00 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Rachel Edelstein, Deputy Assistant Administrator, Office of Policy and Program Development; Telephone: (202) 205-0495, or by Fax: (202) 720-2025.

Background

On June 29, 2016, the Food Safety and Inspection Service (FSIS) published the final rule, “Electronic Export Application and Certification Charge; Flexibility in the Requirements for Export Inspection Marks, Devices, and Certificates; Egg Products Export Certification” (81 FR 42225). The rule can be found online at <https://www.fsis.usda.gov/wps/wcm/connect/3538b05e-151c-4d82-8664-096452a32778/2009-0026.pdf?MOD=AJPERES>, and FSIS notified the World Trade Organization of the rule (G/TBT/N/USA/678/Add.1). The final rule provided for an electronic export application and certification system—the Public Health Information System (PHIS) Export Component—in the meat, poultry, and egg product regulations.

When the PHIS Export Component is incrementally deployed to specific countries, as outlined below, it will provide the following improvements:

- FSIS will electronically inventory and track export certificate information, which will enable FSIS Inspection Program Personnel (IPP) to review exact images (*i.e.*, portable document format (PDF)) of export certification documents prior to approval;
- Exporters will be able to electronically submit, track, and manage applications for export certificates,

including capabilities to bundle multiple applications into a single file;

- Foreign governments will be able to view all export certificates for product intended for their country issued by FSIS in PHIS, as a digital image, through an FSIS-controlled log-in feature, Foreign Country Log-in (FCL).

New Implementation Date

The final export rule stated that FSIS would begin implementing the PHIS Export Component on June 29, 2017. However, to ensure sufficient testing and outreach to all stakeholders, FSIS is delaying the implementation date of the PHIS Export Component to June 29, 2018. On March 27, 2017, FSIS held a PHIS Export Component technical webinar to share information and solicit comments on implementation plans. During and after the webinar, FSIS received requests from industry to delay implementation of the system, to ensure that all stakeholders are prepared and the system is performing effectively. After considering these requests, FSIS agreed to extend the implementation date for an additional year (June 29, 2018). More information from the March 27 webinar, including audio and transcripts, can be found on FSIS’s PHIS Export Component Web page at <https://www.fsis.usda.gov/wps/portal/phis/topics/international-affairs/exporting-products/phis-export-component>.

Country Rollout Schedule

On June 29, 2018, FSIS will implement the PHIS Export Component with a limited number of countries, and then gradually expand implementation to additional countries. Countries will be added incrementally in groups. This Notice announces the first group FSIS intends to include (June 2018; see below for the Group 1 country list). FSIS will announce future groups in advance on the PHIS Export Component Web page at <https://www.fsis.usda.gov/wps/portal/phis/topics/international-affairs/exporting-products/phis-export-component>. Initially, only meat (including Siluriformes) and poultry products will be included in the PHIS Export Component; egg products and casings will be added at a later date, which FSIS will announce in advance through the **Federal Register**, FSIS Constituent Update, or other appropriate means.

Beginning on June 29, 2018, FSIS intends to include Australia, New

Zealand, and the United Arab Emirates (UAE) in Group 1 of the PHIS Export Component. These countries are familiar with technological changes to certification systems; use English; and, in combination, import a moderate amount of the major product classes under FSIS's jurisdiction, giving FSIS sufficient data to assess system performance. Selection of these countries reflects FSIS's consideration of public comments received on topics presented at an April 2, 2015, conference call, which recommended implementing one or more smaller volume, relatively simple certification countries before moving to higher volume, complex certification countries. FSIS welcomes public comment on the selection of these three countries for initial implementation, including feedback on the feasibility of accommodating these countries' certification requirements through the PHIS Export Component process.

In Group 1, FSIS is also including 16 countries that do not maintain meat or poultry requirements in the FSIS Export Library: Afghanistan, Andorra, Bahamas, Bolivia, Burundi, Cape Verde, Cook Islands, Ethiopia, Gambia, Guinea, Liberia, Mozambique, Paraguay, San Marino, Tanzania and Uganda. Additional countries without export library requirements will be added to each group as the Export Component rollout proceeds. FSIS may accelerate or decelerate the schedule, depending on the system's performance. Based on FSIS's experience with implementing other components of PHIS, unforeseen implementation issues may arise, such as the system's performance, training concerns, or questions from importing countries or FSIS IPP. In the first country group, FSIS will be working with foreign governments on a moderate amount of product, rather than on high product volumes that could more severely and unnecessarily disrupt commerce with major trading partners. Starting with low or mid-range volume countries will allow FSIS to build a foundation for more efficient, subsequent implementation with higher-volume countries that have more complex certification processes, for which effective outreach and implementation of the PHIS Export Component will be critical.

Application for Export Certificate

FSIS regulations (9 CFR 322.2 and 381.105) require that the FSIS Application for Export Certificate (FSIS Form 9060-6) be submitted to obtain an FSIS Export Certificate of Wholesomeness (FSIS Form 9060-5). FSIS Form 9060-6 provides FSIS with

important data necessary to certify and facilitate the export of product.

Beginning on June 29, 2018, applicants for export certification to countries included in the Export Component (e.g. Australia, New Zealand, UAE, and 16 listed countries) will complete either (1) an electronic export application in PHIS (i.e. individual application or batch of applications), or (2) send a paper export application (FSIS Form 9060-6) and any required supplemental documents to the FSIS proxy (Urbandale, IA) for data entry into PHIS. Applicants who choose to use paper applications can email or mail the completed application, and any additional information required by the foreign country, to FSIS for entry into PHIS at:

Email: FSCEXport.Recon@fsis.usda.gov.

Mail: U.S. Department of Agriculture, Food Safety and Inspection Service, FMD, Financial Services Center, P.O. Box 9205, Des Moines, IA 50306-9948.

Applicants who choose to use paper applications can only use fax to send the completed application (FSIS Form 9060-6) to FSIS when no additional supplemental documents (e.g. letterhead certificates) are required by the importing country in the FSIS Export Library. Faxes should be sent to: 1-844-378-1048.

As is done currently, in order for FSIS to be able to issue a certificate stating that a shipment meets the country's requirements, applicants are required to submit complete documentation, based on requirements found in the FSIS Export Library, to receive the requested certification.

Regardless of the method the applicant chooses to submit the application, the end result of the export certification process and IPP verification activities will be the same. Starting no sooner than January 1, 2019, FSIS will assess fees for electronic export certificate applications, as is discussed below.

The application process will not change how reimbursable services are charged by FSIS IPP, as described in the 12,000 Series of FSIS Directives on Voluntary Inspection (<https://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/directives/12000-series>). When requested, FSIS provides reimbursable inspection services to accommodate business needs, such as obtaining export certifications necessary to meet requirements of importing countries that are not imposed by FSIS, and are in addition to FSIS requirements.

In PHIS, export applicants can withdraw or cancel an export

application at any point in the approval process prior to IPP approving the export application in PHIS. Once an application is withdrawn or cancelled by the applicant in PHIS, that application is no longer valid for export and is removed from the PHIS user interface. Applicants will still be charged for all applications whether they are processed or withdrawn.

For all countries not yet included in the Export Component, applicants should follow current export application procedures.

Of note, to make the application (FSIS Form 9060-6) more user-friendly, prepare for its use in both a paper and electronic format, better align with commonly accepted international (Codex Alimentarius, CAC/GL 38-2001) guidance and ensure importing country requirements are met, FSIS has revised the data elements within FSIS form 9060-6: Application for Export Certificate. Industry is not to use this revised application until June 29, 2018. Furthermore, FSIS is eliminating a previously approved form associated with the 9060-6—the Product List (FSIS Form 9080-4). Certain limited data elements related to product information will be moved from FSIS Form 9080-4 to FSIS Form 9060-6 (HACCP Category; Maturity Less than 30 months (beef only); Frozen/Shelf-Stable).

Electronic Export Application Fee

The PHIS Export Component will provide new service options to exporters, enabling them to electronically submit, track, and manage their export applications. Therefore, to cover the costs of providing the electronic application and certification service, FSIS established a formula-based fee for electronic export applications submitted in PHIS, under the authority of the Agricultural Marketing Act (7 U.S.C. 1622(h)) and implementing FSIS regulations (9 CFR 350.7; 350.3(b); 362.2(b); 362.5).

The final export rule stated that the formula-based fee for electronic export applications would apply on June 29, 2017; however, to ensure system performance and the accuracy of estimates in the fee formula, FSIS will not begin assessing the fee prior to January 1, 2019, and will recalculate the fee based on the best available estimates for costs and number of applications. The updated fee will be published in the **Federal Register** no later than 30 days prior to its assessment.

As stated in the final export rule, the final electronic export application fee formula is as follows:

Labor Cost (Technical Support + Export Library
Maintenance) + IT Cost (Ongoing Operations and
Maintenance + eAuthentication)

Number of Export Applications

The formula elements, summarized below, are the sum of labor and IT costs, divided by the total number of export applications.

Labor Costs

- *Technical Support:* This cost includes Service Desk support such as resolving user problems with the application services, identifying web browser compatibility issues, and fees from establishments and facilities that request this service.

- *Export Library Maintenance:* This cost includes funding two full-time employees to provide Export Library functions, includes the writing, testing, and maintenance of complex business rules for evaluating the export application that is submitted into the PHIS export system. The business rules allow the system to determine product eligibility before the system accepts the application and transmits it to inspection program personnel. The business rules also facilitate the type of export certification required by the foreign government that will be issued when the application is accepted.

IT Cost

- *Ongoing Operations & Maintenance:* This cost includes improvements and necessary repairs to keep the system responsive to users' needs, including modifying the application based on changes in requirements or user needs, adding functionality based on foreign regulatory changes, upkeep of the system to ensure a secure operating environment that protects the data, and costs to operate the system components. This cost may increase in future years based on General Services Administration (GSA) schedule increases in labor rates and other factors.

- *Level 2 eAuthentication:* This cost is currently zero, but may increase in future years based on a variety of factors, including the number of export business customers annually.

Number of Export Applications: This estimate is the approximate total number of export applications submitted to FSIS annually.

FSIS Export Certificate of Wholesomeness

On June 29, 2018, the PHIS Export Component will have the ability to digitally sign export certificates (FSIS Form 9060-5) from the FSIS certifying official. This feature will provide an additional layer of security for the exporter and the importing country's government. At the time the signature is applied, PHIS will execute security checks to validate that the digital signature is that of the FSIS certifying official. The digital signature will include the printed name of the FSIS certifying official, and the time and date that the signature was applied. This feature, along with other security features of the PHIS export component, such as FSIS-controlled security paper on which certificates will be printed, will provide maximum assurance that export certificates are authentic.

FSIS may also provide certificates signed by FSIS certifying officials with an ink signature, as is done currently. The export certificate, signed either digitally or with an ink signature, will be printed from PHIS on security paper (8½" × 11"), and given to the exporter. FSIS will scan copies of all signed certification documents (e.g. 9060-5, supplemental letterhead certificates) into PHIS before releasing the signed original certification documents to the exporter. Unless specified that a digital signature is required or allowed in the FSIS Export Library, FSIS certifying officials will sign all export documents with an ink signature, as is done currently. Any supplemental documents, such as letterhead certificates, will be printed on standard 8½" × 11" white copy paper.

Of note, FSIS has made limited revisions to data elements in the FSIS Form 9060-5 to better align with commonly accepted international (Codex Alimentarius, CAC/GL 38-2001) guidance and to ensure importing country requirements are met. When additional space for products or statements is necessary with a 9060-5, PHIS will also generate FSIS Form 9060-5A (product continuation page), which is an existing addendum that FSIS has aligned with the revised 9060-5; and FSIS Form 9060-5B (remarks

continuation page), a new addendum to provide more space for additional attestations, when required by the importing country. These updated certification documents will be implemented with the PHIS Export Component, on June 29, 2018.

Country-specific letterhead certificates, and other required supplemental documentation, will not be produced by PHIS. Applicants will complete any required supplemental documents (e.g. letterhead certificates) and upload them to the electronic application in PHIS, or include the supplemental documents with the export package they send to the FSIS proxy.

Batch Processing

The PHIS Export Component will allow exporters to bundle multiple applications, including any supplemental documents (e.g. letterhead certificates) required by the importing country, into a single file, known as batch processing. To maintain system functionality, FSIS reserves the right to place limits on batch processing as needed or required by PHIS. FSIS intends to test batch processing with industry users before implementation to ensure functionality. Upon implementation, FSIS will provide help desk support for batch processing issues (see FSIS's PHIS Export Component Web page at <https://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/exporting-products/phis-export-component> for updates).

Level 2 eAuthentication/Foreign Country Log-In

When the PHIS Export Component is implemented, foreign government officials will have the capability to view all export certificates issued by FSIS in PHIS, as a digital image, for product destined for the government's country, through an FSIS-controlled log-in feature (Foreign Country Log-in, FCL). In addition, the original certificates will be printed on paper and will arrive with the shipment, whether FSIS inspection personnel apply the signature digitally or with ink. Importing government officials will be able to compare digital certificate copies in the FCL with the

original certification documents arriving at the country's port of entry, to verify that the digital certificate copies align with the original certificates arriving with the shipment. A Level 2 eAuthentication account is necessary to access the FCL. An eAuthentication account is the way for a user to interact with USDA Web site portals and applications using a verified identity for each User ID and profile. Prior to implementation of the PHIS Export Component, FSIS will provide further guidance on this process.

USDA Export Stamp

The USDA export stamp bears the export certificate number, and is used to link the consignment to the corresponding export certificate. Beginning on the applicability date of June 29, 2018, FSIS is changing the number of digits in the serial number that appears on both the export stamp and the corresponding export certificate from six to seven numbers. Use of an alternative, alpha-numeric unique identifier in place of the USDA export stamp will be implemented with the PHIS Export Component on June 29, 2018.

eCert

In the future, FSIS also intends to support electronic export certification (eCert) in PHIS. eCert is the government-to-government transmission of certification data and is the electronic equivalent of a paper certificate. When developed and implemented, electronic export certification will allow FSIS to transfer certification data directly to the foreign government's competent authority's certification system.

Group 1 (June 29, 2018)

- Export Library:
 1. Australia
 2. New Zealand
 3. UAE
- Non-Export Library:
 1. Afghanistan
 2. Andorra
 3. Bahamas
 4. Bolivia
 5. Burundi
 6. Cape Verde
 7. Cook Islands
 8. Ethiopia
 9. Gambia
 10. Guinea
 11. Liberia
 12. Mozambique
 13. Paraguay
 14. San Marino
 15. Tanzania
 16. Uganda

USDA Nondiscrimination Statement

No agency, officer, or employee of the USDA shall, on the grounds of race, color, national origin, religion, sex, gender identity, sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, or political beliefs, exclude from participation in, deny the benefits of, or subject to discrimination any person in the United States under any program or activity conducted by the USDA.

To file a complaint of discrimination, complete the USDA Program Discrimination Complaint Form, which may be accessed online at http://www.ocio.usda.gov/sites/default/files/docs/2012/Complain_combined_6_8_12.pdf, or write a letter signed by you or your authorized representative.

Send your completed complaint form or letter to USDA by mail, fax, or email:

Mail: U.S. Department of Agriculture, Director, Office of Adjudication, 1400 Independence Avenue SW., Washington, DC 20250-9410.

Fax: (202) 690-7442.

Email: program.intake@usda.gov.

Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.) should contact USDA's TARGET Center at (202) 720-2600 (voice and TDD).

Additional Public Notification

FSIS will announce this notice online through the FSIS Web page located at <http://www.fsis.usda.gov/federal-register>.

FSIS will also make copies of this **Federal Register** publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to constituents and stakeholders. The Update is communicated via Listserv, a free electronic mail subscription service for industry, trade groups, consumer interest groups, health professionals, and other individuals who have asked to be included. The Update is also available on the FSIS Web page. In addition, FSIS offers an electronic mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at <http://www.fsis.usda.gov/subscribe>. Options range from recalls to export information to regulations, directives, and notices. Customers can add or delete subscriptions themselves, and

have the option to password protect their accounts.

Done at Washington, DC, on: August 31, 2017.

Paul Kiecker,

Acting Administrator.

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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS-2017-0028]

Availability of FSIS Compliance Guideline for Minimizing the Risk of Shiga Toxin-Producing Escherichia Coli (STEC) and Salmonella in Raw Beef (Including Veal) Processing Operations

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice of availability and request for comment.

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing the availability of and requesting comments on the updated compliance guideline for small and very small businesses on reducing STEC and *Salmonella* in beef and veal operations.

The new guideline will assist small and very small beef (including veal) processing establishments understand and comply with the regulatory requirements associated with controlling STEC and *Salmonella* in raw non-intact beef products and beef products intended for non-intact use. The guideline also includes information for establishments and retail stores on developing and maintaining records associated with the production of ground beef.

DATES: Submit Comments on or before November 6, 2017.

ADDRESSES: A downloadable version of the compliance guideline is available to view and print at <https://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/compliance-guides-index> once copies of the guideline have been published.

FSIS invites interested persons to submit comments on this guidance. Comments may be submitted by one of the following methods:

Federal eRulemaking Portal: This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to <http://www.regulations.gov/>. Follow the on-line instructions at that site for submitting comments.